REMARKS/ARGUMENTS

In response to the Office Action of June 2, 2005, Applicants request re-examination and reconsideration of this application for patent pursuant to 35 U.S.C. 132.

Claim Status/Support for Amendments

Claims 39, 40, 42, and 44-46 have been amended. Claims 2-38 were cancelled in a previous response (filed on February 22, 2005). The Examiner has determined that claim 1 is drawn to an allowable product, and thus claims 39-46, previously withdrawn from consideration, have now been rejoined with claim 1, in accordance with the decision in *In re Ochiai*, as they are directed to the process of using the patentable product. Claims 1 and 39-46 are currently under examination and remain pending in the instant application.

No new matter has been added by the amendments to the claims made herein.

Claim 39 has been amended to clearly indicate that the objective of the claimed method is to elucidate essentially all of the biopolymer markers present in a sample such that these biopolymer markers can be identified (see page 35, lines 19-22 of the instant specification as originally filed). Claim 39 has also

been amended to clarify that peptides are identified in a sample by comparison of their mass spectrum profiles with mass spectrum profiles of known peptides (see, for example, page 38, line 22 to page 40, line 8 of the instant specification as originally filed).

Claim 40 has been amended to provide proper antecedent basis for the term "sample" in parent claim 39.

Claim 42 has been amended to define the acronyms for the recited mass spectrometry procedures, MALDI-Qq-TOF, MS/MS, TOF-TOF, and ESI-Q-TOF. These acronyms are well-known to those of skill in the art and are defined in various parts of the specification as originally filed, see, for example, page 10 and page 26, lines 1-2.

Claim 44 has been amended to correct a typographical/grammatical error, "an antibody" replaced "and antibody".

Claims 45 and 46 were amended to provide proper antecedent basis for the diagnostic kit recited in parent claim 44.

Restriction

The Examiner has withdrawn the restriction requirement mailed on November 18, 2004 since all claims which were previously withdrawn from consideration under 37 CFR 1.142 have been rejoined and examined.

Prior Amendments

In the response filed on February 22, 2005, Applicants noted that two documents previously submitted, a preliminary amendment filed on March 8, 2002 and a Response to a Notice to Comply filed on August 20, 2002, do not appear to be entered into the prosecution history of the instant application.

The Examiner indicates that she has reviewed the prosecution history and cannot locate the cited documents. The Examiner invites Applicants to re-submit copies of the documents to complete the record.

In order to complete the record of the prosecution history in the instant application, Applicants submit herewith a copy of the Preliminary Amendment filed on March 8, 2002 and a copy of the Response to Notice to Comply filed on August 20, 2002.

It is noted that computer-readable copies (disks) of the Sequence Listing were submitted in both the Preliminary Amendment filed on March 8, 2002 and in the Response to Notice to Comply filed on August 20, 2002. However, copies of these disks are not provided herein since the current Sequence Listing filed on February 22, 2005 has been determined acceptable to the Examiner.

Claim Objections

Claims 42 and 44, as presented on February 22, 2005, stand

objected to because of the following informalities: Claim 42 uses acronyms. The Examiner asserts that the acronyms should be defined in their first instance to convey Applicants' intended meaning. Claim 44 contains a grammatical/typographical error, "and antibody" should be "an antibody".

The Examiner requires appropriate correction.

Claim 42 has been amended herein to define the acronyms for the recited mass spectrometry procedures, MALDI-Qq-TOF, MS/MS, TOF-TOF, and ESI-Q-TOF. These acronyms are well-known to those of skill in the art and are defined in various parts of the specification as originally filed, see, for example, page 10 and page 26, lines 1-2.

Claim 44 has been amended to replace the phrase "and antibody" with "an antibody" in (b).

Applicants have now addressed all of the Examiner's objections and respectfully request that the objections to claims 42 and 44 be withdrawn.

Rejections under 35 USC 112, second paragraph

Claims 39 and 41, as presented on February 22, 2005, stand rejected under 35 USC 112, second paragraph as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. The Examiner asserts that claim 39 is vague and indefinite because it is unclear as to what a "maximized elucidation" will encompass. Will the sample be profiled or not? The Examiner asserts that it is not clear what other process is intended to maximize the sample profiling. It is suggested that "maximize" be removed from the claim language in order to obviate this rejection.

Applicants respectfully submit that the specification, as originally filed, clearly defines what the phrase "maximized elucidation" intends to encompass.

The SELDI mass spectrometry protocol is used to carry out steps of the claimed method. SELDI mass spectrometry was fashioned upon the principles of retentate chromatography. However, retentate chromatography is limited by the fact that if unfractionated samples are applied to the adsorbent surfaces (chips), the biopolymers present in the greatest abundance will compete for all the available binding sites and thereby prevent or preclude less abundant biopolymers from interacting with the binding sites, thereby reducing or eliminating the diversity of biopolymer markers which are readily ascertainable from the sample (see pages 24-25 of the instant specification as originally filed). Thus, biopolymer markers present in small quantities may not be detected using retentate chromatography.

The instant invention discloses a method for maximizing the

diversity of biopolymers obtained by mass spectrometric analysis of a sample (see page 25, lines 9-13 of the instant specification as originally filed) in other words, the claimed method enables markers present in small quantities within a sample to be detected and identified using SELDI mass spectrometry. This method includes "preparatory steps" which are carried out prior to mass spectrometric analysis, such as chromatography (see page 25, lines 19-22, and pages 40-46 for specific protocols for carrying out "preparatory steps"). Additionally, a noted objective of the instant invention is elucidation of essentially all biopolymer markers in a sample using the preparatory steps prior to a mass spectrometric analysis (see page 35, lines 19-22). Thus, it is readily apparent that the phrase "maximize elucidation" refers to the ability of preparatory steps of the instant invention to enable a greater number of markers to be identified using mass spectrometry, i.e. markers present in high and low quantities will be detected.

However, in the interest of compact, efficient prosecution, claim 39 has been amended herein to remove the term "maximize". Claim 39 has been amended to include the phrase "...elucidate essentially all biopolymer markers..." (see page 35, lines 19-22) in order to point out that the claimed method improves upon the efficiency of conventional SELDI mass spectrometry.

B. The Examiner asserts that in claim 39 step c) the comparison of "characteristic profiles" is vague and indefinite because it is not clear what characteristic is being assessed. The Examiner indicates that if it is the mass spectrum profiles which are being compared, then the claim should clearly set forth this limitation.

Applicants respectfully submit that the specification, as originally filed, clearly discloses that the characteristic assessed is the mass spectral profile of a peptide (see page 1, lines 5-13, page 46, line 22 to page 47, line 10, Figures 2 and 4, and the descriptions of Figures 2 and 4 at page 37).

However, in the interest of compact and efficient prosecution, claim 39 has been amended to further clarify that peptides are identified in a sample by comparison of their mass spectrum profiles with mass spectrum profiles of known peptides (see, for example, page 38, line 22 to page 40, line 8 of the instant specification).

C. The Examiner asserts that claim 41 is vague and indefinite in utilizing the term "blood products". Because the term is not defined in the disclosure the metes and bounds cannot be determined.

Applicants respectfully disagree with the Examiner's contention and contend that the term "blood products" clearly

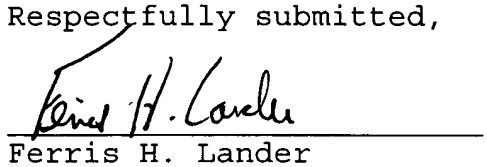
refers to products obtained from breakdown and/or separation of blood into its components, as the term is defined at page 49, lines 7-13.

Accordingly, Applicants have now clarified the metes and bounds of the claims and respectfully request that the rejections under 35 USC 112, second paragraph be withdrawn.

CONCLUSION

In light of the foregoing remarks and amendments to the claims, it is respectfully submitted that the Examiner will now find the claims of the application allowable. Favorable reconsideration of the application is courteously requested.

Respectfully submitted,



Ferris H. Lander
Registration # 43,377

McHale & Slavin, P.A.
2855 PGA Boulevard
Palm Beach Gardens, FL 33410
(561) 625-6575 (Voice)
(561) 625-6572 (Fax)
\\Ns2\SERVER\CLIENT FILES\2100-2199\2132 -Syn-X\2132_000084 - IG Lambda Biopolymer\Amendments\2132_084_AM2.wpd